REMARKS

After entry of this amendment, claims 177 and 196-198 are pending and under consideration. Claims 1-176 and 178-195 have been canceled and new claims 196-198 have been added. Claim 177 has been amended to refer to the 10D5 antibody. Support for the 10D5 antibody and the corresponding deposit number is provided in *e.g.*, paragraph 268. The 10D5 antibody decorates amyloid plaques (*see* US 6,913,745 at col. 69, lines 39-45, previously cited as cited no. 662), and treatment with this antibody as described in the present specification results in reduced burden of Aβ and cell-associated Aβ immunoreactivity (*i.e.*, opsonization) (*see* present specification at paragraph 333). Support for diseases characterized by amyloid deposits of Aβ in the brain is provided at *e.g.*, paragraph 57 and 115. Support for new claim 196 is provided at *e.g.*, paragraph 57. Support for new claim 197 is provided at paragraph 133. Support for new claim 198 is provided at *e.g.*, paragraph 135. No amendment should be construed as acquiescence in the Examiner's position. Applicant uses the paragraph numbering of the office action in responding to the Examiner's comments.

¶2. The restriction requirement is moot in view of claim cancellations.

¶¶5-6. Priority

The Examiner denies priority to US Application No. 09/322,289 and earlier applications because the specification allegedly lacks supports for immunoglobulin peptides that bind to an amyloid fibril, immunoglobulin peptides raised against an immunoglobulin light chain, and immunoglobulin polypeptides that opsonize an amyloid fibril. In reply, all present claims are supported by at least US Application No. 60/080,970 filed April 7, 1998. Support for diseases characterized by amyloid deposits of Aβ in the brain is provided at *e.g.*, p. 9, lines 4-6 and p. 14, lines 20-25. Support for the 10D5 antibody is provided at p. 32, lines 20-25. Support for claim 196 is provided at page 2, lines 36-37. Support for claim 197 is provided at *e.g.*, p. 18, lines 9-12 and 31-33. Support for new claim 197 is provided at *e.g.*, paragraph bridging pp. 19-

20. Support for new claim 198 is provided at *e.g.*, paragraph bridging pp. 19-20. All of the claims are also supported by US Application No. 09/201,430, which incorporates US Application No. 60/080,970 by reference.

¶7. The Examiner alleges that claims 177-180 lack antecedent basis for "immunoglobulin polypeptides," "immunoglobulin light chain" and "opsonizes the amyloid fibril." None of these terms is used in the revised claims. Accordingly, the rejection is moot.

¶8. Claim 177 is objected to for reciting "or a fragments thereof." Such recitation has been deleted so the rejection is moot.

¶¶9-10. Claims 177-184 stand rejected for alleged enablement on the basis that the specification does not enable prophylactic treatment of the disease. The Examiner alleges that based on descriptions of "treatment regimes" and "patients" in the specification, the claims must encompass prophylactic treatment and that enablement of prophylactic treatment would require a showing that patients expected to develop Alzheimer's disease are completely free of the disease and fail to develop the disease after treatment with an antibody as claimed. The Examiner also alleges that the artisan would not be able to determine a therapeutically effective dose because prevention is impossible. The Examiner also alleges that the genus of disease encompassed by the claims includes disease such as amyloid deposit in the kidney that are not morphologically, symptomatically or mechanistically related to Alzheimer's disease.

Although the *specification* does describe prophylactic treatment of patients not yet suffering from an amyloidogenic disease, the present *claim* is directed to treatment of a patient *having a disease* characterized by an amyloid deposit of Aβ in the brain of a the patient. In other words, the disease is already present in the patient being treated. Thus, the Examiner's comments regarding a requirement for evidence of complete prevention of disease in patients not presently having the disease do not address the claims as currently drafted. Likewise the allegation that the artisan could not determine a therapeutically effective dose because complete

prevention is not possible in patients not having the disease does address the claims as presently drafted.

With respect to the Examiner's comments on the claims including diseases characterized by amyloid deposits not related to Alzheimer's disease, the claims have been amended to a subgenus of disease characterized by amyloid deposits of Aβ in the brain of the patient. Such diseases include Alzheimer's diseases and other diseases, such as Down's syndrome, sharing the pathological feature of Alzheimer's disease of amyloid deposits of Aβ in the brain. A treatment that reduces burden of amyloid deposits of Aβ in the brain of a patient is reasonably expected to be of benefit in any disease characterized by such deposits.

¶13. Claims 177 and 179-183 stand rejected as allegedly anticipated by Becker. Becker is alleged to teach administration of antibodies to Aβ for treatment of Alzheimer's in therapeutically effective amounts. The Examiner acknowledges that Becker is silent as to whether an antibody opsonizes an amyloid fibril but alleges that this is an inherent property. This rejection is respectively traversed, particularly as applied to the amended claims.

Becker does not disclose or suggest the 10D5 antibody. Becker proposes various assays by which antibodies to treat Alzheimer's disease might be identified but does not disclose any specific antibody that has been or would be identified as a result of performing those assays.

¶14. Claims 177-184 stand rejected as anticipated by Solomon. As discussed above, the present claims are entitled to a priority date of at least April 7, 1998, which antedates Solomon's earliest date under § 102(e). Thus Solomon is not prior art under § 102(e).

Applicant notes that in prosecution of Solomon's own case, Solomon has attempted to antedate related patents having a common priority claim to the present patent by means of a 37 CFR § 131 declaration. (The full prosecution of Solomon is available on PAIR, but can be provided if the Examiner requests.) The 131 declaration describes experiments purporting to show that an antibody to a kappa light chain reduces an amyloidoma injected into the body of a mouse. The specifics of the experiment are unclear from the declaration, but if the

experiment is of the same type as discussed in Solomon, US 2003/0147882, the amyloidoma was a kappa light chain amyloidoma injected between the scapula (*i.e.*, not into the brain of a mouse). Such an experiment does not provide any evidence that antibodies are capable of clearing a deposit in the brain of a mouse, much less treating a disease characterized by deposits of Aβ in the brain, and thus should be ineffective to antedate the present claims or disclosure or that of related patents.

¶15. Double Patenting

¶16. Claims 177 and 179-184 are rejected for obviousness type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,743,427. Applicant proposes the issues be held in abeyance until indication of allowability in the present case. Applicant will then provide a terminal disclaimer over cited patent provided the cited claims are in conflict with those in the present case at this time.

¶17. Claims 177 and 179-184 are rejected for obviousness type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,761,888. Applicant proposes the issues be held in abeyance until indication of allowability in the present case. Applicant will then provide a terminal disclaimer over cited patent provided the cited claims are in conflict with those in the present case at this time.

¶18. Claims 177 and 179-184 are rejected for obviousness type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,913,745. Applicant proposes the issues be held in abeyance until indication of allowability in the present case. Applicant will then provide a terminal disclaimer over cited patent provided the cited claims are in conflict with those in the present case at this time.

¶19. Claims 177 and 179-184 are provisionally rejected for obviousness type double patenting as being unpatentable over claims 1-19 of U.S. Application No. 09/322,289. Applicant proposes the issues be held in abeyance until indication of allowability in the present case. Applicant will then consider providing a terminal disclaimer over cited case provided the cited case has been or is about to patented, the claims in the cited case have not been divided

from those in the present case by restriction requirement or election of species, and the claims in the cited case are in conflict with those in the present case at this time. Applicant notes that an Appeal Brief has been filed in U.S. Application No. 09/322,289.

¶20. Claims 177 and 179-184 are provisionally rejected for obviousness type double patenting as being unpatentable over claims 1-46 of U.S. Application No. 10/890,070. Applicant proposes the issues be held in abeyance until indication of allowability in the present case. Applicant will then consider providing a terminal disclaimer over cited case provided the cited case has been or is about to patented, the claims in the cited case have not been divided from those in the present case by restriction requirement or election of species, and the claims in the cited case are in conflict with those in the present case at this time.

¶21. Claims 177 and 179-184 are provisionally rejected for obviousness type double patenting as being unpatentable over claims 1, 56-82, 85-89 and 91-92 of U.S. Application No. 10/788,666. Applicant respectfully points out that U.S. Application No. 10/788,666 is abandoned thus the rejection is moot.

¶22. Claims 177 and 179-184 are provisionally rejected for obviousness type double patenting as being unpatentable over claims 164-229 of U.S. Application No. 10/923,469. Applicant proposes the issues be held in abeyance until indication of allowability in the present case. Applicant will then consider providing a terminal disclaimer over cited case provided the cited case has been or is about to patented, the claims in the cited case have not been divided from those in the present case by restriction requirement or election of species, and the claims in the cited case are in conflict with those in the present case at this time.

¶23. Claims 177 and 179-184 are provisionally rejected for obviousness type double patenting as being unpatentable over claims 164-204 of U.S. Application No. 10/923,267. Applicant proposes the issues be held in abeyance until indication of allowability in the present case. Applicant will then consider providing a terminal disclaimer over cited case provided the cited case has been or is about to patented, the claims in the cited case have not been divided from those in the present case by restriction requirement or election of species, and the claims in the cited case are in conflict with those in the present case at this time.

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¶24. Claims 177 and 179-184 are provisionally rejected for obviousness type double patenting as being unpatentable over claims 1-81 of U.S. Application No. 10/979,701. Applicant respectfully points out that U.S. Application No. 10/979,701 is abandoned thus the rejection is moot.

¶25. Claims 177 and 179-184 are provisionally rejected for obviousness type double patenting as being unpatentable over claims 1, 4, 6-8, 14, 15, 18-24, 32, 35-37, and 56-76 of U.S. Application No. 10/923,469. Applicant respectfully points out that U.S. Application No. 10/923,469 is abandoned thus the rejection is moot.

Respectfully submitted,

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